

REMARKS

Claims 12-24 are pending. Claims 1-11 have been canceled without prejudice or disclaimer.

Although the claims have been revised from the content that was rejected in the outstanding Office action, the claims as amended will be discussed in terms of the distinctions over the prior art applied in the previous Office action. The examiner will note that claim 12 is the only independent claim pending and is distinguished from the applied prior art in at least the following ways.

Claim 12 is directed to an inhalation device that comprises, inter alia, “an air inlet flow path, by inhalation of a user, for introducing to the chamber outside air and for injecting outside air toward the pharmaceutical composition to apply an air-generated impact to the pharmaceutical composition.” In the claimed invention, a pharmaceutical composition is pulverized into fine particles by using the inhalation of a user to inject outside air toward the pharmaceutical composition. In contrast, the device of Smith et al. (U.S. Patent No. 5,785,049) uses a high pressure gas stream to pulverize a pharmaceutical composition that has been entrained in the air flow induced by the high pressure gas stream. The claimed invention is different in both structure and operating principle from the device described in Smith et al.

Unlike the claimed inhalation device that pulverizes a pharmaceutical composition into fine particles by an air-generated impact that is applied by outside air by inhalation-induced pressure when the user inhales air, the device of Smith et al. uses a high pressure gas stream (introduced at port 50 in Fig. 2) that is not directed to the powdered medicament located in the receptacle 12, but induces air to fluidize and transport powdered medicament toward the outlet end of path 46 (Fig. 2) where the gas

stream provides sufficient shear energy to substantially break up agglomerates to create an aerosolized powder in the plume capture chamber 30 (see col. 5, lines 20-41; col. 6, lines 29-43; Fig. 2). The Smith et al. device is configured such that outside air is induced into the device, not by inhalation of the user, but by the pressurized gas stream introduced at port 50. In addition, Smith et al. teaches that particle agglomerates are broken up by the force of the pressurized gas, not by air that is induced into the device by inhalation of the user. Accordingly, Smith et al. does not teach an inhalation device comprising “an air inlet flow path, by inhalation of a user, for introducing to the chamber outside air and for injecting outside air toward the pharmaceutical composition to apply an air-generated impact to the pharmaceutical composition” as required in claim 12 and claims dependent thereon.

Claim 12 is further distinguished from the teachings of Smith et al. based on the recitation of “an auxiliary flow path for inhaling outside air which does not flow via the chamber, the auxiliary flow path opening around the inhalation flow path in the direction of the air flow of the inhalation flow path such that the auxiliary air flowing out from the auxiliary flow path does not disturb the air flow of the inhalation flow path.” This feature is described in the original specification, for example, at page 24, line 20 to page 26, line 5. Smith et al. does not teach such an auxiliary flow path as recognized by the Examiner in the outstanding Office action.

As noted in the reply to the previous Office action, the Sladek (U.S. Patent No. 6,039,042) inhalation device is both structurally and functionally different from the claimed invention and the device of Smith et al. Sladek does not teach the auxiliary flow path of the invention recited in claim 12, and claims dependent thereon, since the

openings (24) in Sladek identified by the Examiner are used to discharge air to the outside, not to inhale outside air.

Moreover, the auxiliary flow path of claim 12, and claims dependent thereof, is required to open “around the inhalation flow path in the direction of the air flow of the inhalation flow path such that the auxiliary air flowing out from the auxiliary flow path does not disturb the air flow of the inhalation flow path.” With such a structure and arrangement, the claimed inhalation device can help prevent the particles of the pharmaceutical composition from adhering to the wall surfaces along the flow path. Neither Sladek nor Smith et al. teach such a feature.

Although not relied on by the Examiner, Applicants have considered the embodiment shown in Figs. 12(A) to 12(C) of Smith et al. This patent describes an embodiment where the path (120) (Fig. 12B) operates as an air inlet flow path in the first step of creating a plume, and then operates to create a reverse flow of air (Fig. 12C) through the chamber as the patient inhales from the plume chamber. See col. 13, line 36 to col. 14, line 5 of Smith et al. The claimed invention, however, is further distinguished from this embodiment of Smith et al. by requiring that the auxiliary flow path for inhaling outside air does not flow via the chamber.

For all the reasons discussed above, claims 12-24 are not obvious over Smith et al. and Sladek.

The only other patent relied on in the outstanding Office action is Praud (U.S. Patent No. 5,497,765). Praud does not teach or suggest any of the deficiencies of Smith et al. and Sladek discussed above, and is not important in establishing a prima facie case of unpatentability of the claimed invention.

Prompt and favorable reconsideration of this application is respectfully requested.

If there is any fee due in connection with the filing of this Reply, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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